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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/648,092	06/21/1996	JOHNSTON W. MCAVOY	UNSYD-39709	8661
24201	7590	09/12/2006		
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			EXAMINER FAY, ZOHREH A	
			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/648,092

Applicant(s)

MCAVOY ET AL.

Examiner

Zohreh A. Fay

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-33 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-28 and 39-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Art Unit: 1618

Claims 14-28 and 39-41 are presented for examination.

The remarks, declaration and exhibits filed on June 21, 2006 have been received and entered.

Claims 14-28 and 39-41 are again rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on pages 2-4 of the office action of January 26, 2005.

Claims 14-28 and 39-41 are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth on pages 2-3 of the office action of December 19, 2005.

Claims 19-23 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 92/17206 for the reasons set forth on page 4 of the office action of January 26, 2005.

Applicant's arguments and declarations have been carefully considered, but are not deemed to be persuasive. Applicant in his declaration argues that on or before November 19, 1993 it was known by the ordinary skill in the art that the biological activity of TGF-B may be inhibited by TGF-B inhibitors. Applicant also argues that on or before November 19, 1993 there were several assays for TGF-B described in the art including assays where TGF-B had an inhibitory effect on cellular proliferation. Applicant further refers to other assays for determining if a compound is a TGF-B inhibitor. The arguments are not well taken. Because of the known unpredictability of the art, and in the absence of sufficient experimental evidence, no one skilled in the art would accept the assertion that instantly claimed agents can be used for the treatment of cataract or after cataract formation as inferred by the claims and contemplated by the specification. What the specification does not do however is the necessary link between TGF-B inhibitors and actually finding the inhibitors, which are capable of treating cataract and,

Art Unit: 1618

after cataract formation. In short, although the applicant describes assays for determining whether a given compound possesses certain desired characteristics, and identifies some broad categories of compounds that might work, these descriptions, without more precise guidelines, amount to little more than "a starting point, a direction for further research" *Genetech v. Novo Nordisk*, 108 F. 3d 1361, 1366 (Fed. Circ. 1997). The specification does not describe the claimed invention in terms that will enable a person of ordinary skill in the art to attempt to discover how to practice the claimed invention. *Rochester* 68 USPQ2d at 1438. The instant specification embraces a potentially almost infinite number of undefined potential candidate compounds, and have not identified more than a few having TGF- β inhibitory activity, let alone how to make and use such other compounds. Applicant's arguments regarding the 102 (b) rejection have also been carefully considered but are not deemed to be persuasive. Applicant alleges criticality to the topical ophthalmic composition of the claimed invention in comparison to the composition taught by the prior art. The allegation is not well taken. To use an old composition for a new purpose does not create a patentably distinct composition in the absence of evidence to the contrary. A composition reads on a compound and a pharmaceutical acceptable carrier. The intended use or the route of administration does not create a new composition.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1618

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh A. Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1618

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

Zohreh Fay